DAIRY FOOD SAFETY

FACTORY REQUIREMENTS

Tasmanian Dairy Industry Authority

2023

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OVERVIEW

Food Standards Australia New Zealand is a statutory authority that works with the Australian, New Zealand, State and Territory governments to set ***legally enforceable food*** standards that are set out in the Food Standards Code (the Code), which is divided into chapters:

- Chapter 1 of the Code contains general food standards that apply to all foods
- Chapter 2 contains compositional standards for particular classes of foods
- Chapters 3 and 4 contain food safety requirements for the production and processing of food, and requirements for premises and vehicles used for food production.

Under Standard 4.2.4, *The Primary Production and Processing Standard for Dairy Products,* dairy businesses are required to control the potential food safety hazards associated with their business by developing, documenting and effectively implementing a food safety program. Particular measures to be covered by the food safety program are also specified.

Licensees are responsible for ensuring their food safety system is developed, documented, approved, implemented, maintained, monitored and audited as determined by the TDIA.

These Factory Requirements have been developed to help licensees and prospective licensees understand the general intent of relevant clauses of Standards 1, 2, 3 and 4.2.4 of the Code.

The Commonwealth Department of Agriculture, Forestry and Fisheries (DAFF) *Export Control (Milk and Milk Products) Rules 2021,* also apply to export registered dairy processors.

Some Acts, Regulations and Codes that may affect Tasmanian dairy processors include:-

- *Tasmanian Dairy Industry Act 1994*
- *Food Act 2003*
- *Export Control (Milk and Milk Products) Rules 2021,* published by DAFF
- *Pathogen Management Guidelines*
- *Food Standards Australia New Zealand Food Standards Code*
- Relevant parts of the Building Code of Australia including Tas Part H102
- Specific Council requirements

Useful Websites

Tasmanian Dairy Industry Authority	www.tdia.tas.gov.au
Dairy Industry Act 1994	www.thelaw.tas.gov.au
Food Standards Australia New Zealand	www.foodstandards.gov.au/foodstandards/foodstandardscode/
Food HACCP	www.foodhaccp.com/indexcopy.html
Dairy Australia	www.dairyaustralia.com.au
Dept of Health & Human Services	www.dhhs.tas.gov.au/publichealth/foodsafety
Dept of Agriculture & Water Resources	http://www.agriculture.gov.au/export/controlled-goods/dairy
Dairy Food Safety Victoria	www.dairysafe.vic.gov.au
Codex Alimentarius Commission	www.fao.org/docrep/W8088E/w8088e00.htm
CoP Gen Principles of Food Hygiene	www.mhlw.go.jp/english/topics/importedfoods/guideline/dl/04.pdf
Dept Health, Victoria	http://www.health.vic.gov.au/foodsafety/bus/templates.htm

This is an evolving document which reflects progress in food law, science, technology and process control systems. To maintain its currency, it is reviewed annually. It is possible that between reviews, amendments to its contents may be issued. It is important that users of this document assure themselves they are using the current food safety legislation. Detailed information may be found by visiting the sites above and other relevant sources.

INTRODUCTION

The Requirements have been prepared to help new and existing dairy processors develop a food safety management system; to demonstrate their knowledge of their dairy food processing responsibilities, to control food safety hazards and produce safe food. It is based on the principle of prevention, rather than detection, as described in Standard 3.2.1, Food Safety Programs, of the Food Standards Code and the Codex Hazard Analysis and Critical Control Point (HACCP) system, rather than relying on end product testing.

As a licensed dairy processor you must:

1. Demonstrate skills and competencies in food safety, relevant to the duties being undertaken (including HACCP training for at least one person),
2. Develop and implement a TDIA-approved food safety program,
3. Comply with your food safety program,
4. Have a HACCP plan for each product line approved by the TDIA **prior** to manufacture (including product trials), and notify the TDIA **prior** to any changes to HACCP plans,
5. Comply with written corrective action requests issued by a TDIA auditor within the stated timeframes in the request,
6. Notify the TDIA of the detection of human pathogenic organisms, or if inhibitory substances exceed the MRL, by fax, phone or email within 2 working days after the initial indication of the result. Written details of such incidents must be provided within 3 working days,
7. Purchase all dairy produce from a licensed farmer or licensed processor,
8. Maintain and make available upon request by the TDIA such records as are necessary to enable the TDIA to audit and verify information provided by you to the TDIA. This includes access to original data held by your testing laboratory,
9. Have your milk and liquid milk products transported by a Food Standards Code compliant milk collection and transportation business, or TDIA licensed vendor/distributor,
10. Notify the TDIA prior to making any significant changes to your program, management personnel, premises, fixtures, fittings and equipment,
11. Notify the TDIA within 14 days of any changes to your dairy farmer supplier data base,
12. Pay the prescribed licence fee, and fees payable on behalf of dairy farmers, in accordance with *Dairy Industry Regulations 2004*

You are advised to check on any external requirements that may apply; for example, you will need to notify your local Council. You may wish to contact the Business Licence Information Service (BLIS) at the Department of Economic Development for more information.

During the planning and budgeting processes – and ongoing throughout the year – you must determine and ensure the availability of adequate and appropriate financial, physical and human resources necessary to meet your licence conditions.

Food safety legislation is forever changing and you must ensure you keep up to date with the latest information; changes may have occurred since the compilation of this Guideline.

For further information or assistance please contact:-
Tasmanian Dairy Industry Authority
1 – 3 Rundle Road, Stoney Rise, Tasmania 7310
Phone: (03) 6421 7689
Email: enquiries@tdia.tas.gov.au

REQUIREMENTS OF A FOOD SAFETY PROGRAM

As a licensed dairy processor, you take responsibility for ensuring that you have documented methods and means to make your food safe in how it is made, produced, transported or sold. It is your responsibility to understand your legal requirements and decide how to best meet the food safety requirements in a way that works for you. Your food safety program will demonstrate how you are going to meet those requirements. You can be fined for not keeping records and for not meeting other legal responsibilities.

The Food Safety Program will help you to:

- identify when food can become unsafe
- take steps to avoid food becoming unsafe
- implement practices in your business to keep food safe
- use records to monitor food safety and to demonstrate that your business routinely follows these practices
- ensure staff have the skills, knowledge, and competency to handle food safely.

Hazard Analysis Critical Control Point (HACCP) is a systematic, preventive approach to food safety that monitors and manages hazards, rather than relying on finished product inspection.

A *Hazard* is a biological, chemical or physical agent that will cause harm to a consumer; *Risk*, considers the likelihood and severity of a hazard occurring.

A TDIA-approved HACCP Plan must be developed for each product line.

Some Food Standards Code provisions, in addition to HACCP include:

1. Management Responsibility
2. System Review – Management and Internal Audit
3. Document and Data Control
4. Approved Supplier/Sourcing Program
5. Training
6. Process Control
7. Cleaning and Sanitation
8. Pest Control
9. Product labelling, identification and traceability
10. Control of nonconforming product/Corrective Action,
11. Recall procedure.
12. Water Quality
13. Premises and Equipment – installation, calibration and maintenance procedures
14. Health and Hygiene
15. Product Sampling and Analysis
16. Shelf Life Testing
17. Minimum Sampling and Product Testing

1. MANAGEMENT RESPONSIBILITY

Refer to FSANZ Food Standards Code, Standard 3.2.1, Food Safety Programs, clause 5,

Details of your business

- business name and licence/registration number,
- name of proprietor(s) (the person(s) or company that owns the business)
- address and contact details of the business.

Nature of your business
A clear outline of the nature or activities of your business, including a description of each product you produce.

Responsible persons
Provide a list of key personnel who affect safety and legality, their roles and functions in relation to the FSP. This must include the person(s) responsible for the overall implementation and management of the FSP, and alternative delegates.

Such a list ensures that all key roles and functions are covered and that all staff understand their responsibilities. It also provides an indication of the need to review the list should staff leave the business, or operations change.

Auditing of the food safety program
Specify how often the food safety program will be audited, by whom (in your business), what will be audited, where the outcome and any corrective action is recorded. See Section 2, System Review.

Quality Policy Statement and Food Safety Culture
The business owner or manager must document, sign and date a policy stating the business intent about food quality, food safety, and food safety culture.

The policy will describe the company's commitment to continuous improvement, ensure resources are available, that staff possess the necessary skills, knowledge and competence to perform their duties, and the business has the capacity and capability to fulfil customer and legal expectations.

This policy must be in a prominent location and understood by all staff.

A strong **food safety culture** is created when people understand the importance of making food safe and commit to appropriate practices to achieve that goal. It involves top-down and bottom-up commitment. Everyone has an important role in food safety – their behaviour will determine whether your food is safe and suitable.

List the product(s) and processes covered by the FSP; their start and end points.

Organisation Structure
A current and accurate organisational chart shall be available which identifies all the management and staff positions within your organisation. The chart should show the relationship from top management to all staff who have a responsibility for quality or food safety.

Position Descriptions
The responsibilities and authority of all staff who have a responsibility for quality or food safety must be documented, including alternate delegates.

2. SYSTEM REVIEW

FSANZ Food Standards Code 3.2.1, 3(e), 4(a) 5(e)

Clause 5(e) of Standard 3.2.1 requires the food safety management system to **provide for the regular review of the entire food safety program by the food business to ensure its adequacy**.

A review ensures that your food safety management system is meeting its objective of controlling all potential food safety hazards that are likely to occur at each step of production.

The review may consist of rolling audits scheduled to look at different parts of the FSP over time so that the entire system is audited annually. The internal audit program should include regular housekeeping/Good Manufacturing Practices inspections. These audits should be conducted in a systematic way, with an audit checklist, or calendar, listing the items audited, identification of non-conformances, follow up and close out of non-conformances**. A record of the audit and any corrective actions must be kept.**

The food safety program must include information about the review of the program, such as:

Who is responsible for the review

When the review took place

What was reviewed

The outcome must be recorded and

What corrective action, if any, was taken as a result of the review

Internal Audit and Management Review

The review should consider:

- results of all audits,
- follow-up actions from previous management reviews,
- customer feedback,
- status and operation of the food safety system,
- process performance and product conformity,
- status of preventive and corrective actions,
- planned changes that could affect the quality management system, and
- corrective action or recommendations for improvement.

The outcome of the review is to ensure ongoing compliance of the FSP with legislative requirements and safe food outcomes.

Internal Audits – Verification of Food Safety Programs is available by visiting the Dairy Food Safety Victoria web site. It describes what internal audits are and why they should be performed, and includes practical points to consider when preparing and conducting internal audits.

Also visit Dept Health, Victoria, Record Sheet 13.

3. DOCUMENT AND DATA CONTROL

FSANZ Food Standards Code 3.2.1 5(f)

Your food safety program must **provide for appropriate records to be made and kept, demonstrating action taken in relation to, or in compliance with, the FSP.**

These records must provide sufficient information to show that you are complying with your FSP. Records must be legible and indicate:

- what the record relates to (title)
- where there is more than one page, number of pages.
- who made the record
- the date and issue status
- the result of what is being recorded
- any action taken as a result of the recording such as a corrective action

Document control is important because obsolete information needs to be distinguishable from current information. Otherwise it is possible work could be carried out according to superseded specifications, process controls or methods.

Documents must be made available to staff and at locations where operations essential to the effective functioning of the food safety system are performed.

Records pertaining to the food safety system must be kept for a minimum of 4 Years.

4. APPROVED SUPPLIER PROGRAM

Food Standards Code 3.2.1, and 3.2.2 5(1 to 4)

The supplier approval process is required for all products and services that could affect the safety and suitability of products produced. The ASP ensures items sourced are *safe*, meet the specified *quality* requirements and comply with all *regulatory* requirements.

The methods for selecting, evaluating, approving and monitoring an Approved Supplier must be documented. This could be as simple as a good supply history, sourcing from accredited suppliers; a letter of guarantee – Statutory Declaration, or Certificate of Analysis.

The procedure must address the following:

- Evidence of the ability of your suppliers to provide the desired service/standards, e.g. FSPs or Certificates of Analysis, as above,
- Methods for selection and approval of suppliers and “emergency suppliers”,
- Methods for removal from the approved program,
- A list of approved suppliers, their products/services and their status must be maintained.

Ensure chemical and microbiological specifications for all incoming goods and services are agreed between yourself and the supplier, documented and maintained. Temperatures of all potentially hazardous raw materials must be recorded at receival.

Where incoming goods or services are not meeting specification, corrective and preventive action must be documented and records maintained.

5. SKILLS AND KNOWLEDGE

FSANZ Food Standards Code 3.2.2 (3)

Persons who undertake or supervise food handling operations must have skills in food safety and food hygiene and knowledge of food safety and food hygiene according to their work activities.

Staff must be supervised, instructed and/or trained in food hygiene matters appropriate to their role. Those responsible for developing and maintaining the food safety management system must be suitably trained in the principles and application of Pre-Requisite Programs (PRPs) and Hazard Analysis and Critical Control Points (HACCP).

You must make sure that staff taking part in the relevant processes demonstrate sufficient skills and are aware of the hazards identified and of the critical points in the production, storage, transport, processing and/or distribution process. They must also show awareness of the corrective measures, the preventive measures and monitoring and recording procedures applicable in the business, in accordance with procedures documented in the food safety management system.

Employees who operate/manage Critical Control Points (CCPs) must be trained in the procedures based on the HACCP principles appropriate to their tasks (e.g, a filler operator will need hygiene training, while a pasteuriser will need additional training in the procedures based on HACCP principles). Refresher training and its frequency should be considered according to your business needs and demonstrated skills.

You must document details of how you will provide adequate resources and competent staff to ensure these requirements are met. This includes appropriate training for all staff, with particular emphasis on those responsible for monitoring and controlling CCPs.

TDIA cannot issue a licence to an applicant with insufficient skills as this can present a risk to food safety.

Training options include:

- On-the-job training under a more experienced staff member,
- Recognition of people's experience in food businesses,
- Self instruction using on-line or written material, and
- Running in-house training sessions.

The Responsible Person or Supervisor on site must have received adequate training in HACCP accreditation from a TDIA-approved training organisation.

Even though training has been provided to a staff member, it does not guarantee that he or she will have the appropriate skills and knowledge required for the position. This procedure shall include a review of staff competence as part of the **internal audit program**. For example:-

- Staff training needs
- Details of what training is provided for new employees e.g. induction, hygiene, cleaning
- Refresher training
- Training courses for supervisors and specialist positions eg:
    - Principles of Food safety
    - HACCP awareness
    - Pasteuriser operation
- Instructions, work procedures and food safety induction for all employees
- Details on the frequency of training and how you assess competence of the employee
- How effectiveness of the program will be evaluated and at what frequency.

Refer to the DFSV website: An overview of the training requirements of dairy manufacturing staff

6. PROCESS CONTROL

FSANZ Food Standards Code 3.2.2 clauses 7(1 - 4) and 3.2.3, cl 12

You must process and produce safe and suitable food.

Clause 15 of Chapter 4.2.4, Processing of milk and dairy products, specifies that the processing of milk and dairy products must include a pasteurisation step, or heat treatment equivalent to pasteurisation, to reduce any pathogenic micro-organisms that may be present in the raw milk to a safe level. For the processing of milk, additional requirements apply, such as being cooled immediately to prevent the growth of microorganisms.

Clause 16 specifies that processing to make cheese must include a pasteurisation step, or equivalent processes to eliminate pathogens 16 (b & c).

Clause 17 – 35 specifies additional requirements for the manufacture of raw milk cheese, including primary production, storage, transport, and processing requirements.

Procedures for the validation and verification of heat treatment should be incorporated as an integral part of your food safety program.

Pasteurisation is a Critical Control Point and your food safety program must document your processing controls, including time, temperature or other specifications, as well as calibration, validation and verification, monitoring, corrective actions and supporting records.

Minimum requirements for the pasteurisation and heat treatment of milk and dairy products are contained in *ANZDAC - Validation and Verification of Heat Treatment Equipment and Processes,* which is available by contacting the TDIA.

Any pasteurising equipment must be validated by an appropriately qualified technician to show effectiveness, and the results provided to TDIA with the application for licence.

New applicants must contact the TDIA to ascertain pasteuriser requirements, including applicable Standards, such as AS 3993-2003.

Cheese in oil - the risk of botulism – PDF DFSV
Provides information on the potential risk of introducing *Clostridium botulinum* when adding herbs, spices and vegetables to cheese in oil.

Allergens must be considered as part of your food safety management system since they are public health hazards. After defining which allergens are relevant for a certain product, a preventive strategy can be based on 2 approaches:

i. Allergens should be kept out of the premises by guarantees from the suppliers of raw materials and other ingredients; or

ii. Strict measures to minimise cross-contamination should be applied with products potentially containing allergens separated from other products at the time of production, by the use of different or segregated production lines, receptables and storage facilities, by a specific work methodology, awareness of workers and compliance with hygiene rules before returning to work from breaks for eating.

If such a preventive strategy cannot be efficiently implemented, the production process might have to be reconsidered. Hazards must be managed and any identified or potential risks prevented or eliminated.

7. CLEANING AND SANITATION

FSANZ Food Standards Code 3.2.2 19(1, 2), 20(1, 2) and 4.2.4 cl 13

Food processors must maintain food premises, fixtures, fittings and equipment to a high standard of cleanliness and sanitation.

Clean premises and equipment are fundamental to the production of safe, quality food – it is critical for all post-processing contact surfaces and ancillary equipment. ***Clean*** is defined by FSANZ as **"*clean to touch and free from visible extraneous matter and free from odours*."** It must also be free from allergens.

Absorbent surfaces permit absorption of food residues and allow for harbourage and growth of microorganisms. Timber is not permitted in processing environments for this reason. Surfaces that are cracked or poorly finished are difficult to clean and sanitise and allow microbes to colonise. Access of services through walls, if not properly sealed, are hard to clean and allow ingress of microbes and pests.

Work instructions must be developed, documented and implemented.

These shall include all production and storage areas, fixtures and fittings, all equipment used for food manufacture, all cleaning equipment, amenity areas and transport facilities.

The procedures shall include as a minimum:

- The name of the equipment or area
- The frequency of cleaning
- Who is responsible for the cleaning
- When the item / area is to be cleaned
- Cleaning equipment required
- Chemicals required, the concentrations used and contact times and temperatures
- Methodology for the cleaning
- Equipment required for safety during the cleaning process (PPE)
- Records to indicate that cleaning was carried out (for example daily check list)
- Key inspection points for cleaning verification
- Consideration of sequence of cleaning to avoid recontamination of clean equipment
- Corrective actions to be taken and records of these actions when they occur.

Details shall be given for equipment strip down and accessibility requirements for effective cleaning. Reference shall be made to maintenance support if this is required for an effective equipment strip down for cleaning and rebuild for production. Photos should be used in the documentation as visual aids.

FAT TOM is an acronym used to describe the six favorable conditions required for the growth of foodborne pathogens: **F**ood, **A**cidity, **T**ime, **T**emperature, **O**xygen and **M**oisture.

Also, for cleaning and sanitation; **WATCH** – **W**ater, **A**ction, **T**ime, **C**oncentration and **H**eat

Developing a cleaning and sanitising program - PDF DFSV

A documented cleaning and sanitising program plays a key role in preventing the contamination of dairy food. Also see Dept Health, Victoria, *Cleaning and Sanitising*, and Record 8.2 *Cleaning Schedule.*

8. PEST CONTROL

FSANZ Food Standards Code 3.2.2, clauses 19 (1, 2), 20 (1, 2) and Standard 4.2.4, cl 13

You must eradicate and prevent the harbourage of pests. Pest management and control must be continuous and effective.

You must have in place a documented pest management program which includes a schedule for the application and frequency of treatments.

Effective programs combine different treatment methods to get the best overall result: preventative methods and control methods.

Preventative methods work by minimising access to food and shelter:

- remove clutter such as grass, obsolete equipment, and stacks of pallets.
- make sure that food is tightly sealed.
- make buildings pest-proof.

Control methods work by repelling or killing the pests:

- fly traps and electronic fly killers.
- non-poisonous traps for mice/rats or poisonous baits for mice/rats.

Pest control must not create food safety hazards.

The program shall also include:

- Bait maps depicting the type and location of treatments.
- Safety Data Sheets (SDS) shall be maintained for any pest control chemical that is being used on site.
- Who is responsible
- Records of monitoring and corrective action shall be maintained
- How often are the baits/control stations serviced, reviewed
- Where an external pest control contractor is used, obtain a copy of the contractor’s licence.

Dairy Food Safety Note 6, *Introduction to Pest Control Programs,* is available on the Dairy Food Safety Victoria web site. Provides guidance and references to help manufacturers adopt a pest control program that will ensure dairy food is protected from contamination by pests, and the pesticide chemicals involved in controlling them.

Also refer to Dept Health, Victoria, *Pest Control*.

9. PRODUCT LABELLING AND IDENTIFICATION

FSANZ Food Standards Code Chapter 1.2 and Standard 4.2.4 clause 14

You must have an effective traceability system to be able to trace inputs and food one step back to your supplier and one step forward to your customer.

Supplier traceability is particularly important in the event a food safety problem is discovered by your supplier and you need to identify which products you received from them. You need to keep the following information for all products supplied to you:

- Name, address and contact details of supplier,
- Accurate description of product supplied
- Traceability information for the product supplied (date, batch code, etc.)
- Date of delivery

This information may be contained on the invoices, receipts or dockets you get from your supplier

You must have an effective *customer traceability* system, i.e. be able to trace food one step forward to your customer. This is particularly important if you identify a food safety problem with products you have supplied to your customers. You need to keep the following information:

- brand name and description of the food product, including package size and type of packaging
- use by or best before date
- lot identification (batch or serial number)
- quantity of the batch manufactured and the date and amount released
- quantity of the affected food product that can be accounted for
- distribution within Australia (including a distribution list and the types of premises at which the food is likely to be sold)

It is useful to provide a photo or other image of the food product to help identify it.

Refer to *Overview of Food Labelling*, *Guide to Food Labelling and other Information Requirements* and *Food Labels – What Do They Mean?*

http://www.foodstandards.gov.au/consumer/labelling/documents/Food%20Labels%20Posterfinal%20.pdf on the FSANZ website. This site provides Country of Origin labelling information.

Part 1.2 *Labelling and other Information Requirements* is available by visiting the FSANZ website. You can also refer to Schedule 7, *Trade Descriptions*, of the Export Control (Milk and Milk Products) Rules 2021.

Product identification and traceability - PDF DFSV
An overview of the requirement to have a functional traceability system that ensures safe food, and aids in the removal of unsafe food from the marketplace.

Your labelling must accurately reflect the contents of the package it is applied to.

You must validate the Nutrition Information Panel by conducting relevant tests at least annually.

10. CORRECTIVE AND PREVENTIVE ACTIONS/CONTROL OF NON-CONFORMING PRODUCT

FSANZ Food Standards Code 3.2.1 5(d), HACCP Principle 5

A *corrective action plan* is a strategy detailing action to correct or eliminate a problem that has occurred or been identified as having potential to occur. A *preventive action plan* defines the steps necessary to eliminate the root cause to prevent it from recurring. It is important to establish Corrective and Preventive Action (CAPA) because correcting and preventing problems early will cost significantly less than fixing them later.

Corrective and Preventive Action must be developed, documented and implemented to define *who* is responsible, *what* action is to be taken, *when* it will occur, *where* in the process (and where recorded) and *how* it will be done with any affected product, what is to be done with product produced between the noncompliance and previous acceptable results, and what will be done to prevent a recurrence (Root Cause Analysis).

CAPA consists of two stages: First, immediate action needs to be taken for any product that may be unsafe or unsuitable because the hazard is not under control. If monitoring shows the critical limits have not been met, the corrective actions specified in the food safety program need to be followed. Corrective actions may include disposal or reprocessing of the product.

Second, there needs to be an investigation into the probable cause of the 'loss of control' of the hazard so that steps can be taken to make sure this incident does not happen again. Changes may be required to the food safety program arising from the investigation.

A process for escalation when corrective actions are not completed within the allocated timeframe must be documented.

Non-conforming product includes raw materials, work in process and finished product that does not meet specification. It also includes equipment that has been found to be non-conforming.

You must document how you will label and identify products and equipment that are rejected or quarantined pending the results of inspection, and how and where you will dispose out of specification products.

The procedures or practices adopted could include some, or all, of the following:-

- The designation of an area for the storage of non-conforming stock. The perimeter could be marked and/or be distinguished with appropriate signage.
- Using stickers or signs that identify the status of the product. Signs such as "**HOLD**" etc. should be sufficient, as long as staff are aware of their significance and adequate records kept.
- Records of disposition of any affected product.

It is recommended that you develop and document a procedure showing how customer complaints will be received, investigated and responded to, and describe the methods used to investigate the complaint. Retain records of customer complaints and their investigation.

The procedure will outline the responsibility for investigating customer complaints, initiating follow up actions and communicating back to the customer how the complaint has been resolved. Procedure should include criteria for the determination of the validity of complaints.

Records of complaints should include corrective actions.

11. PRODUCT RECALL AND TRACING PROCEDURES

It is a legal requirement under Standard 3.2.2, clause 12, and Standard 4.2.4, cl. 14, that a food business engaged in the wholesale supply, manufacture or importation of food must –

(a) have in place a system to ensure the recall of unsafe food;

(b) set out this system in a written document and make this document available to an authorised officer upon request; and

(c) comply with this system when recalling unsafe food.

The *Food Industry Recall Protocol*, 7th Edition, May 2014, published by FSANZ, sets out what should be done, when in the interest of public health and safety, food products should be removed from supply or use by consumers. In addition to this, the Protocol offers an example of a written recall plan, which may be used as a template or illustration of what a working plan needs to entail.

Once the decision to recall a product has been made, there are three primary objectives:

1. stop the distribution and sale of the affected product as soon as possible
2. inform the TDIA, State Recall Action Officer and FSANZ Recall Coordinator (all recalls) and the public (consumer level recalls only) of the problem
3. effectively and efficiently remove potentially unsafe food from distribution and sale

Key steps in conducting a successful recall are:

- obtain and consolidate all necessary information about the food product
- determine the level of recall required
- notify relevant parties, including the TDIA within 24 hrs, confirmed in writing within 72hrs
- retrieve the food product from the market place
- dispose of the food product
- report on the recall, including the action taken to prevent a recurrence of the problem

A traceability system for products and ingredients must be used. The intent is to trace the movement one step backwards and one step forward.

You should be able to provide the following information in order to conduct an effective recall:

- nature of the problem
- brand name and description of the food product, including package size and type of packaging
- use by or best before date
- lot identification (batch or serial number)
- quantity of the batch manufactured and the date and amount released
- quantity of the affected food product that can be accounted for
- distribution within Australia (including a distribution list and the types of premises at which the food is likely to be sold)

It is useful to provide a photo or other image of the food product to help identify it.

A **withdrawal** is action taken to remove food from the supply chain where there is no food safety risk or the food safety risk has not yet been confirmed. You must notify the TDIA of withdrawals within 72hrs of commencing the withdrawal.

If you supply major retailers, they need to be advised and you may wish to complete the Australian Food and Grocery Council's (AFGC) Australia and New Zealand product recall/withdrawal form which is available from the AFGC's website.Link to Recall Templates - Recall templates (foodstandards.gov.au)

12. WATER QUALITY

FSANZ Food Standards Code 3.2.3 4

Water must be sampled and tested in accordance with TDIA-approved frequency.

Your FSP must detail the requirements for sampling, testing and obtaining test results for water.

- Unless otherwise agreed with the TDIA, monthly microbiological testing must be done.
- Physico/Chemical test results, against the Australian Drinking Water Guidelines, can be obtained from TasWater at a minimum annually.

Other events which should automatically trigger testing of water:

(a) When work has been done on sewage or water piping ,

(b) When you commission new refrigerators or ice makers or after breakdowns and repairs,

(c) When there has been flooding or heavy rains which may cause ingress or siphonage,

(d) When there is obvious discolouration of the water, or it has an offensive odour or oily film.

Procedures should include:

- Rotation of sampling points through all water sources
- How the sample is taken (aseptic sampling techniques),
- Who can take the sample, including the training and approval of sample takers,
- The checks to ensure that sample and results are at the stated frequency,
- Map of the water supply and supply points at the registered establishment,
- Notification to TDIA in the event of failure to comply with the micro.
- System for holding product produced when the water does not comply
- Potable water must not contain any *Escherichia coli* in 100mL

In systems where disinfection is used, evidence of continuous operation is very important in providing assurance of microbial quality. Disinfection is very effective against bacterial pathogens but less so against viruses and enteric protozoa (e.g. Giardia and Cryptosporidium), where filtration is more effective. The presence of viruses and protozoa can be minimised by protecting water supplies from human and livestock waste.

Standard 3.2.3, Clause 4(1), *Food premises must have an adequate supply of water if water is to be used at the food premises for any of the activities conducted on the food premises.*

An adequate supply of water is defined to mean potable water that is available at a volume, pressure and temperature that is adequate for the purposes for which the water is used.

13. PREMISES, EQUIPMENT, CALIBRATION AND MAINTENANCE

Your premises, facilities, equipment and vehicles must meet the requirements of Standards 3.2.2 and 3.2.3, and clause 13 of 4.2.4 of the Food Standards Code and relevant sections of the National Construction Code.

The layout of your premises must minimise opportunities for food contamination. You must ensure that your premises, fixtures, fittings, equipment and transport vehicles are designed and constructed to be effectively cleaned and, where necessary, sanitised.

The premises must be provided with the necessary services of water, waste disposal, light, ventilation, cleaning and personal hygiene facilities, storage space and access to toilets.

As a general guide:-

Floor

The floor shall be a smooth, durable, free-draining, non-slip surface that is impervious and free from cracks and other defects, easily cleanable and no ponding of water.

You may wish to consult Table 3.1 '*Suitability of Floor Finishes for Food Premises Areas'* of AS 4674:2004 – 'Design, construction and fit-out of food premises'.

Australian Standard (Floors) – AS/NZS 4586:2004 – 'Slip resistance classification of new pedestrian surface materials' is also useful as this provides details on slip resistance for floors.

Please note that floor grading for a floor waste is to be evenly graded (e.g. 1:100) to ensure suitable fall. Depending on the use of the premises there may be other gradients that are applicable e.g - for wet-down areas. The BCA should be consulted in this instance.

Walls

The walls shall have a surface that is smooth, rigid and durable, impervious and free from cracks and other defects. Walls shall be finished in a light colour (to facilitate cleaning), and if the surface does not consist of a glazed material it shall be painted with washable full gloss paint.

You may wish to consult Table 3.2 '*Suitability of Wall Finishes for Food Premises Areas'* of AS 4674:2004 – Design, construction and fit-out of food premises.

Coving – Floor/Walls

The angles of all walls and floors of the preparation area shall be coved and sealed. This is to be done in such a manner as to prevent moisture through the joints, facilitate cleaning and ensure that accumulation of dirt, grease, etc, does not occur.

You may wish to consult Section 3.1.5 *'Coving'* of AS 4674:2004 – 'Design, construction and fit-out of food premises'.

Ceilings

Ceilings shall consist of a smooth, rigid surface that is free from cracks and other defects.

Ceilings shall be constructed in such a manner that offers the least possible opportunity for the lodgement of dust and shall be finished with light coloured, washable full gloss paint (to facilitate cleaning).

You may wish to consult Table 3.3 '*Suitability of Ceiling Finishes for Food Premises Areas'* of AS 4674:2004 – Design, construction and fit-out of food premises.

Window Sills

Where windows are present, windowsills are to be splayed down at an angle (e.g - 45°) and not used as a shelf. This facilitates cleaning and prevents the accumulation of dust and other particles. Sills should be at least 300mm above benches, sinks and appliances.

Animals and Pests

Pests must be prevented from entering the premises by providing screens, self-closing doors and other inhibiting mechanisms to all openings, doorways and windows which may be opened e.g - air-curtains or electronic fly traps.

It is important to note that precautionary measures must be taken to ensure that pests will not be a problem in a food business.

Lighting

The preparation and storage areas shall be provided with natural or artificial lighting (or both). A minimum light intensity of 200 lux is r*ecommended*. Artificial lighting is to comply with AS/NZS 1680.1:2006 and AS/NZS1680.2.4:1997.

All lights should be fitted with light diffusers/covers or shatterproof tubes to facilitate cleaning and to prevent contamination of food and the premises should breakage occur.

Ventilation

Adequate natural or mechanical ventilation shall be provided to effectively remove fumes, smoke, steam and vapour from the premise.

Positive pressure ventilation, in accordance with AS/NZS 1668.1:1998 and AS 1668.2-2002, may be provided to remove and prevent the accumulation of excessive heat, steam and moist vapours.

Plinths

All appliances and fixtures that are *not* capable of being easily moved should be installed so that the area underneath the article can be easily cleaned. If this is not possible, they are to be placed on a solid base constructed of smooth, impervious, easily cleanable material (plinth).

It is recommended that plinths be constructed at a minimum of 75mm in height.

Steel legs and frames used for supporting such appliances and fixtures must be non-corrodible and have the ends of tubular steel sealed to prevent product build-up, microbial contamination, and vermin and insect access.

Shelving

The surface of all shelving shall be smooth, impervious, non-absorbent, non-corrodible, free from cracks and defects, and capable of being easily cleaned. Shelving for food storage should not be at a level lower than 250mm above the floor.

If the underside of the shelving is absorbent, it is recommended that the surface be sealed so that it meets these requirements.

Supports and Brackets

Sinks, tubs, draining boards, handwash basins, heaters, urns, benches, shelving and similar fittings shall be non-corrodible and supported on approved frames. If hollow pipe is used the ends must be sealed. Timber framing is not permitted.

Handwash Basins

A separate handwash basin is to be provided with a permanent supply of warm running water through a single outlet. A non-hand operated system is preferred (e.g – sensor operated).

Handwash basins should be located and installed so that they are unobstructed, easily accessible and no further than 5m from any food handling activity.

The hand wash basin is to be of a size that allows for the effective washing of hands and arms. A minimum recommended size is 400mm x 500mm off the wall.

Hand sanitiser and a hygienic means to dry hands shall be provided. A receptacle for used paper towels is to be provided.

Services Pipes and Conduits

All service pipes are to be concealed in floors, plinths, walls or ceilings. Where this is not possible, such pipes are to be fixed on brackets so as to provide at least 25mm clearance between the pipe and adjacent vertical surface and 100mm between the pipe and adjacent horizontal surfaces.

Where pipes enter into the wall cavity, gaps must be sealed.

AS 4674 – 2004 Design, construction and fit-out of food premises is *useful for small dairy processors* when read in conjunction with the relevant food safety standards and BCA.

EQUIPMENT CALIBRATION

The purpose of calibration is to determine by comparison with a standard of known accuracy, the value of each reading from a particular measuring instrument. You must demonstrate that all equipment used to inspect, measure or test the product is reading accurately so that the results of these readings can be relied upon.

Thermometers may be calibrated against boiling water and ice-water. Scales may be verified with a check weight of known accuracy. The check weight must be validated annually.

You must develop a procedure to address products produced between the time equipment is discovered to be out of calibration and the last satisfactory calibration check.

A **CALIBRATION SCHEDULE** must include the following:

- Uniquely and indelibly identify all equipment that requires calibration
- Frequency of calibration.
- Method of calibration, when done and when due
- Determine how accurate the measurements need to be
- A method of identifying equipment that is out of calibration
- Corrective action necessary for product produced whilst equipment was out of calibration
- Who is responsible for undertaking calibration

A **PREVENTIVE MAINTENANCE program** is used to ensure that there is a planned and documented approach to the ongoing maintenance of premises and equipment. This preventative approach reduces the likelihood of equipment failure during manufacturing operations and also minimises contamination of product from faulty or deteriorating structures or equipment.

The maintenance program should include the following information:

- the maintenance procedures for premises and equipment
- records to indicate that maintenance procedures have been followed
- corrective actions to be taken if maintenance procedures have not been followed
- date maintenance issue was identified
- description of maintenance issue
- date maintenance issue was or will be rectified.

Hygienic Design: Guidelines for dairy food manufacturing premises, **Building Construction Guidelines,** and **Maintenance Programs** provide information to help in planning and developing premises that are fit for processing dairy products are available by visiting DFSV's website.

14. HEALTH AND HYGIENE REQUIREMENTS

Food handlers can be a direct source of contamination if good hygienic practices are not followed or if they are suffering from a foodborne illness and are engaged in food handling activities where there is a reasonable likelihood of contamination.

Standard 3.2.2, clauses 13, 14, 15, 16, 17 and 18 specifies the health and hygiene requirements of food handlers and food businesses to ensure the safety and suitability of food. The measures must be documented in the FSP under a health and hygiene program or policy.

Personal hygiene practices are measures that food handlers take to avoid contaminating milk or dairy products or any food contact surfaces. Contamination could occur from foreign objects, microorganisms or chemicals that are transferred through direct contact with milk or dairy products or because of contaminating surfaces that contact the product.

Personal hygiene requirements should include:

- a hand washing policy (how and when hands are to be washed and dried)
- rules regarding clothing , hair and jewellery
- where on the premises eating/smoking is or is not permitted
- avoiding unnecessary contact with the product
- requirements for covering cuts and wounds.

Personnel that have symptoms of foodborne illness, or know that they are suffering from or are carriers of a foodborne disease, must not be involved in activities where there is a reasonable likelihood they could contaminate food. Symptoms of foodborne illness include diarrhoea, vomiting, sore throat with fever, fever or jaundice.

Foodborne diseases that can be transmitted via food contaminated by infected handlers include gastroenteritis, hepatitis A, salmonellosis and campylobacter enteritis.

The procedures to be followed when food handlers involved in food handling activities have symptoms of, or are suffering from a foodborne illness, should be documented in the food safety program. This should cover,:

- what to do about personnel working if they report that they are unwell
- which illnesses or conditions mean a person is unable to undertake certain activities

Warm water for hand washing

Warm water must be provided for hand washing unless you have a specific exemption under clause 14 of Standard 3.2.3.

Warm water for personal washing is usually within the range 20ºC – 40ºC. The temperature is not critical provided it is not so hot that it scalds and not so cold that people are reluctant to use it.

15. PRODUCT SAMPLING AND ANALYSIS

You need to identify those with responsibility for sampling, inspecting and testing finished product and identify how you collect samples and test them.

All finished product testing should be undertaken in a competent laboratory. The types of testing conducted on finished product should be documented in the finished product specification.

Staff should be qualified, trained, and competent to conduct sampling, inspection and analysis and listed in your FSP. You will need to keep records of all tests, whether a product has failed or passed, and what corrective action was taken when the product failed.

Testing costs may be reduced by compositing samples (i.e., testing multiple samples as a single sample), provided the test does not become less sensitive by doing this.

Don't composite different products which may confuse or give a misleading result. Don't composite more than 5 samples. The lab needs to know when samples are to be composited. The lab may be able to composite aseptically to avoid contamination. Adverse results mean that each individual sample will need to be retested.

Minimum Test Frequency* – Individual Product Lines

Factory Rating	Annual milk intake (L)		
	< 60,000	60,000 – 360,000	>360,000
A	2 monthly	Monthly	Fortnightly
B	Monthly	Fortnightly	Weekly
C	10 consecutive batches, then weekly for 4 weeks, then revert to test frequency based on factory rating		

New licensees and new product lines must demonstrate safe food credentials (process verification) by providing finished product test results equivalent to a 'C' rated factory.

Additional requirements apply to products manufactured from unpasteurised milk.

Products with post-pasteurising additives must be tested for additional microorganisms.

When a product fails the standards, the product line that failed to meet the standard must be sampled and tested until five consecutive batches meet the standards.

If a pathogen is detected in dairy product, the Pathogen Management Guidelines must be implemented.

* Please visit file (dairysafe.vic.gov.au) and refer to the Technical Information Note on Microbiological Testing Criteria.

Or visit the Food Standards Code Compendium of Microbiological Criteria for Food (foodstandards.gov.au) to access the Compendium of Microbiological Criteria for Food

16. SHELF-LIFE TESTING AND NUTRITION INFORMATION PANEL

Where products are labelled with “Use by” or “Best-Before Date”, a schedule for the verification of shelf-life testing (micro and sensory) shall be implemented and carried out on each product annually.

Refer to *A Guide to Calculating the Shelf Life of Foods*, NZMPI, and the Guide to Standard 1.2.5 - *Date Marking of Packaged Food,* on the FSANZ website.

Nutrition Information and any claims made on the label attached to your product must be verified. Chemical composition, fat, moisture, salt and pH, as appropriate, must be undertaken at least annually.

17. CODEX HACCP REQUIREMENTS – ALIGNED WITH S 3.2.1, FOOD SAFETY PROGRAMS

The application of HACCP is the central focus of all TDIA-approved food safety programs. It involves the systematic identification and assessment of hazards and the measures for their control to ensure the safety of dairy food. HACCP is the major tool for the risk analysis of food safety elements in the manufacture of dairy products, focusing on prevention rather than end product testing. Go to Codex Alimentarius website and Chapter 5 Part 1 Section 5 of the Milk and Milk Product Rules.

The following steps of the Codex HACCP Guideline and shall be included as part of this process.

The HACCP Team (Step 1 of Codex HACCP)

Identify and document the members of the HACCP team, who are those with the process skills and knowledge to develop and maintain the HACCP Plan. At least one HACCP team member, should have attended a training course in HACCP Principles, or equivalent.

Scope and Purpose of your HACCP Plan (Step 1 of Codex HACCP)

The scope of the HACCP Plan shall be defined and documented, including the start and end point of the process(es) within the HACCP Plan, and the products covered by the HACCP Plan.

The purpose shall include the intent that all food safety hazards will be identified and controlled.

You can cover quality, environmental, occupational health and safety, or other risk considerations within the scope of your HACCP System, if you wish.

Product Description and Intended Use (Steps 2, 3 of Codex HACCP)

Develop and document a Product Description and Intended Use for all products within your product scope. 'Like' products that are processed in similar ways may be grouped together in the one Product Description. Products that are processed differently require a separate Product Description. Each Product Description shall cover the following criteria:

- Description of product
- Composition
- Physical/chemical structure
- Microcidal/static treatment including method of preservation
- Packaging – primary & secondary
- Storage, handling & distribution methods
- Chemical and biological composition
- Salt, moisture, pH, fat content, as relevant
- Shelf life
- Intended Use of the product(s);
- Labelling requirements (as per Food Standards Code)
- Sensitive consumers – presence of allergens

Prepare a **full description** of the dairy product - including relevant information about the ingredients, the physicochemical properties (*e.g.* pH, salt concentration, water activity) and how it is prepared, packaged, stored. The following table is an *example* of a product description proforma.

Product name **(full name of finished product)**	**Low-fat yoghurt (plain)**
Ingredients	Whole milk, skim milk powder, live culture
Chemical Composition: Fat Protein Carbohydrate (sugars) Sodium	 4.0% fat 9.0% protein 4.0% carbohydrate (2.3% sugars) 30 mg sodium pH <4.5
Microbiological Composition E. coli Listeria monocytogenes Coagulase-positive Staphylococci Yeast and Moulds	 < 10/ g Not Detected in 25 g <100/ g < 200/ g
Processing overview	• Raw milk & skim milk powder to achieve 20%total solids • Product mix stirred and heated to 88°C and held for 5 minutes • Cooled to 42°C and inoculated with starter culture comprising *Lactobacillus bulgaricus* and *Streptococcus lactis* • Fermented for ~8 hours at 42°C to ensure the final pH is <4.5 • Cooled to 5°C, transported to the filling machine, packaged and labelled, and placed in cold room at 5°C
Method of Preservation	Yoghurt is made from pasteurised milk, and has a pH <4.5 and is stored at refrigeration temperatures (5°C) for the duration of its shelf-life
Packaging	Packaged and sealed in plastic tubs: Volumes: 110ml, 600ml, and 1 litre
Allergen advice	Contains milk and milk products
Storage conditions	4°C
Shelf life	21 days
Distribution	Cool room on premises then to supermarkets via wholesaler in refrigerated van

The intended use of the product must be described, reflecting the expected manner in which the consumer will use the product. Identify vulnerable groups (*e.g.:* aged, infants, allergenic consumers).

Product	**Low-fat yoghurt (plain)**
Intended use	The low-fat product is unsweetened and may be consumed with complementary ingredients such as fruit or nuts Maybe also be consumed as a snack, or as an ingredient in dips and sauces
Condition before consumption	Stored refrigerated May be brought to room temperature before consumption
Consumers	General population including the young, elderly and pregnant women

A procedure for identifying, **monitoring and managing allergens** must be developed, documented and implemented.

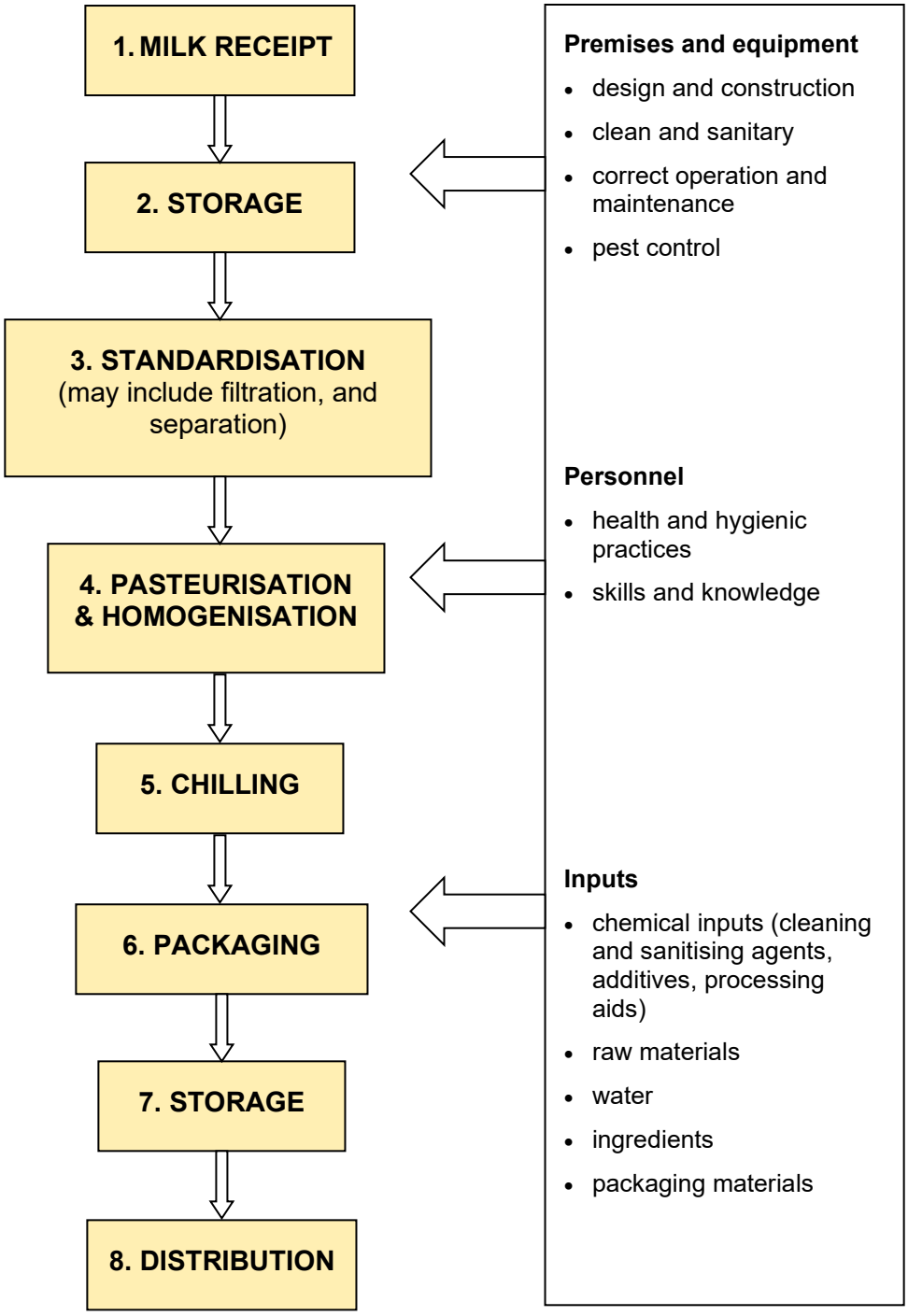
Allergens present a very real threat to immuno-compromised consumers. The information you provide is the only means a consumer can determine the safety of your product.
Packaging must be labelled with an allergen warning where required. For more information, visit Allergen Bureau

Process Flow Chart (Steps 4, 5 of Codex HACCP)

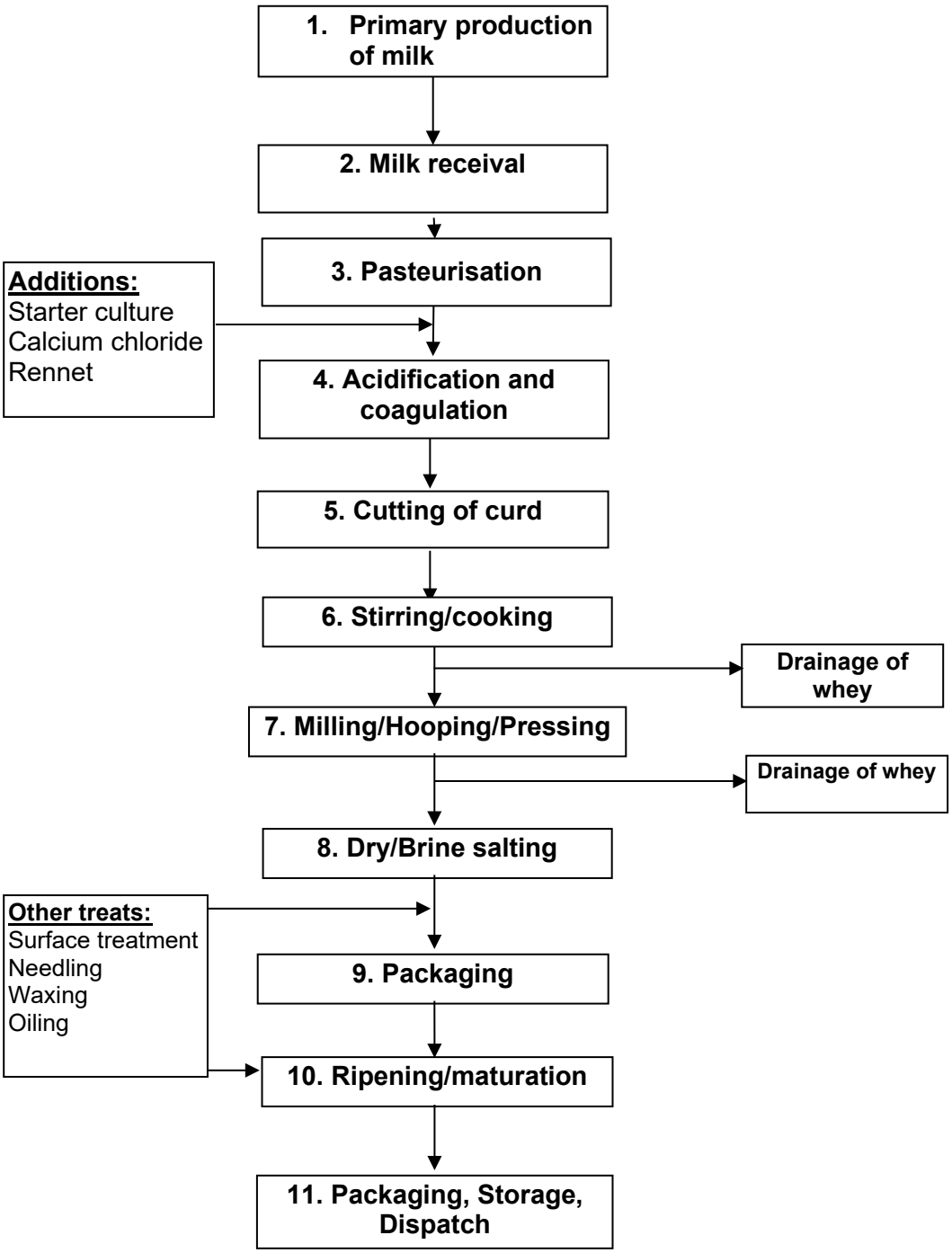
All the major steps in the process (or processes) shall be identified, numbered and documented on a flow diagram. If there are any significant inputs at a particular step, they shall also be identified on the flow diagram. Examples of inputs include water, rework etc.

Once developed, the HACCP Team must verify the accuracy of the Flow Diagram on site and the team leader sign the diagram.

Key steps involved in packaged milk processing



Overview of major steps in the manufacture of cheese



Hazard Identification, Analysis and Control (Step 6, Principle 1 of Codex HACCP)

Hazard analysis is the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and must be addressed in the HACCP Plan.

The matrix below allows a more consistent approach to determine the significance or otherwise, of any identified food safety hazard (chemical, biological or physical). This then allows the identification of CCP status control measures at a glance i.e., For those control measures developed to eliminate, prevent or reduce significant hazards for an acceptable level at least one must be a CCP (even though it may occur at a later step in the process).

Severity (Health Effect)

Likelihood (Relative Risk)

A. Common occurrence

B. Known to occur or "it happened at our premises"

C. Could occur or "I've heard of it happening" (published information)

D. Not likely to occur

E. Practically impossible

Consequence (Health Effect)	**Likelihood** (Risk)				
	A. Common occurrence	**B.** Known to occur	**C.** Could occur	**D.** Not likely to occur	**E.** Practically impossible
1 Can cause fatality	**1**	**2**	**4**	**7**	11
2 Can lead to serious illness	**3**	**5**	**8**	12	16
3 Can cause a product recall	**6**	**9**	13	17	20
4 Customer complaint	**10**	14	18	21	23
5 Not significant	15	19	22	24	25

A value of 1-10 (shaded) indicates a significant (Critical) hazard, which signifies that control measure(s) must be put in place. Hazards that are not significant will have values of 11-25 and are generally managed by pre-requisite programs.

It is up to the HACCP team to determine whether it makes good sense to have any control measures in place (ie CP status control measures) to further reduce the risk of the hazard.

By recording the values in the Hazard Analysis worksheets, others, including food safety auditors can then better understand the logic applied by the original HACCP team.

At each step, consider the **5 'Ps'**

Product (including ingredients and packaging introduced at that step)

Premises (the potential hazards from the immediate environment)

Plant (the potential hazards introduced by the equipment and services)

Procedure (the potential hazards introduced by the methods)

People (the potential hazards introduced by the staff themselves)

Determining Critical Control Points (Step 7, Principle 2 of Codex HACCP)

A Critical Control Point (CCP) is a step in the process at which control shall be applied to eliminate a food safety hazard or reduce it to an acceptable level. A CCP is an action taken as part of the process flow, and may not be a control measure as already identified.

The CCP must identify all the process steps where control is necessary to eliminate or reduce a food safety hazard, and shall be applied consistently to all process steps.

HACCP Audit Table

A HACCP Audit Table shall be developed, documented, and applied which includes each step of the process(es). It shall list all the CCPs identified in the Hazard Analysis, and shall include the following requirements:

Establish Critical Limits (Step 8, Principle 3 of Codex HACCP)

A critical limit is a criterion that separates acceptability from unacceptability. If the critical limits for a CCP are exceeded, a hazard may exist.

Monitoring of CCPs (Step 9, Principle 4 of Codex HACCP)
Monitoring is the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Monitoring procedures shall define:

- **who** will undertake the monitoring (this person must be trained);
- **what** will be monitored;
- **where** monitoring will occur; and
- **how** critical limits will be monitored.
- **when,** frequency of the monitoring;

To ensure monitoring is effective and compliant, the following points should be implemented:

- Monitoring procedures should provide real time measurements and not rely on lengthy test methods such as microbiological assessments requiring extended incubation times if the product has to be held pending a result at the CCP.
- Monitoring equipment (e.g. thermometers, scales, pH meters, etc.) should be selected to record data within an appropriate range and be calibrated to a recognised standard.
- Monitoring records must be kept and all monitoring activities recorded. A supervisor should review and sign the records daily.

CCP Corrective Actions (Step 10, Principle 5) see earlier in the Guideline

Decide and record:

(a) **What specific corrective actions** will be taken to:

(i) bring the Critical Limit under control;

(ii) deal with affected product that was produced while the process was out of control;

(iii) investigate the cause to avoid a repetition of the problem.

(b) **Who** is responsible for carrying out the corrective actions;

(c) What information is to be recorded, where and by whom; and

(d) Who will check that corrective action is carried out properly and where and how this check is recorded.

All corrective actions must be documented in the food safety program.

Verification Activities (Step 11. Principle 6 of Codex HACCP)

Verification procedures are required to ensure that the HACCP System is being followed and is effective. As a minimum, the verification activities that shall be undertaken include: internal audits, HACCP plan review, microbiological and chemical testing (where applicable), shelf life testing (where applicable), finished product assessments (where applicable), and review of monitoring and corrective action records.

Record Keeping (Step 12, Principle 7 of Codex HACCP)

A system of record keeping relevant to the HACCP Plan shall be documented and implemented. All records associated with the HACCP System shall be retained including:

- Monitoring of CCPs (and QCPs);
- Corrective actions taken regarding CCPs (and QCPs);
- Changes to the HACCP system;
- Verification Activities

Records shall be retained for a minimum of 4 years.

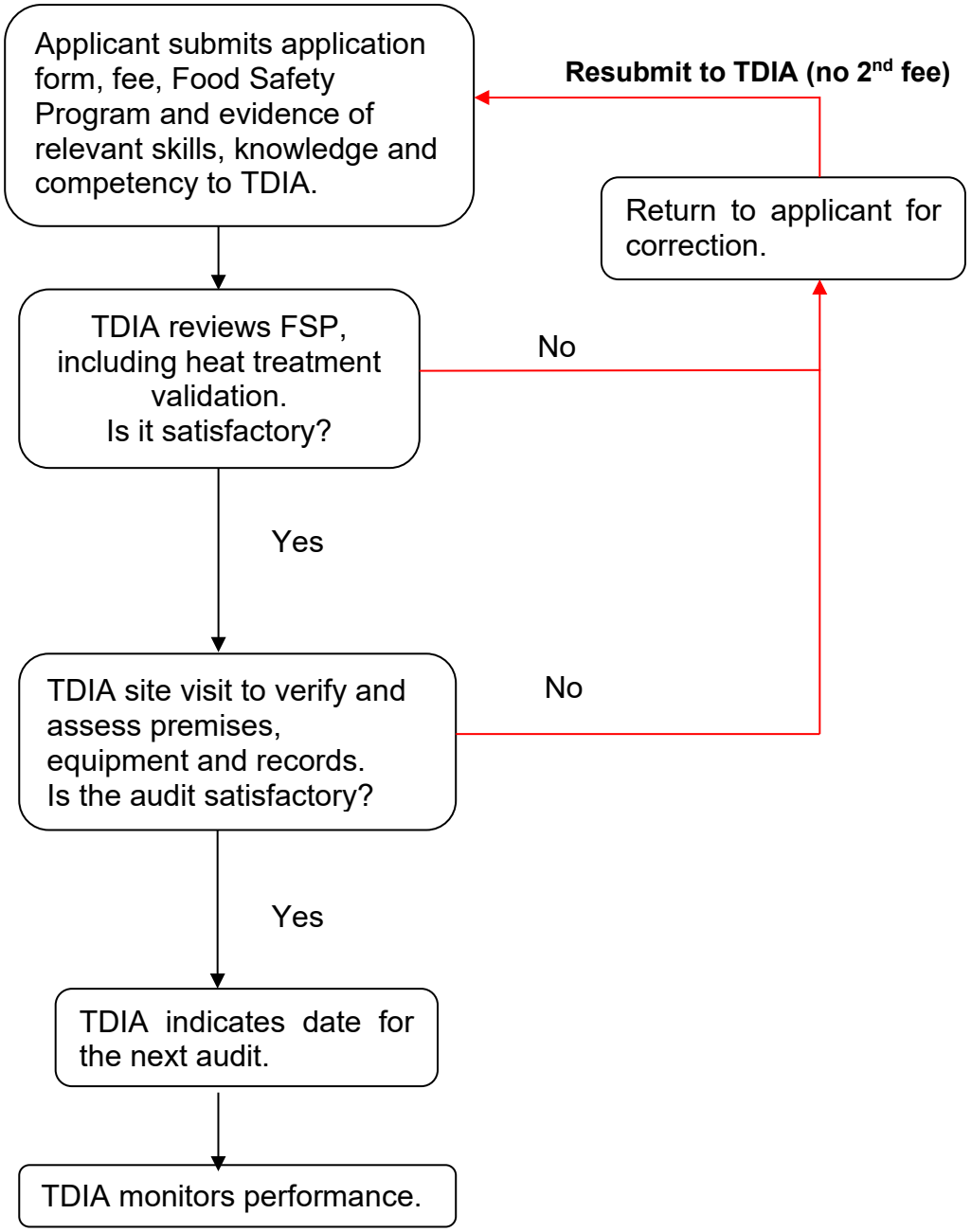
Hazards, control, monitoring, corrective action and records set out in a table as per the examples below;

These tables are to be used as a guide only;

Critical Control Point	Hazard	Critical Limit	Monitoring	Corrective action
Pasteurisation	Microbiological (survival of pathogenic microorganisms)	Milk is to be pasteurised to a temperature of at least 72˚C for at least 15 seconds.	**What** Check time/temperature readouts **Who** Pasteuriser operator **When** Each batch **How** Comparison of Indicating thermometer and chart recorder. Calibration records **Where Records** Charts and logs Time/temperature readouts (may be electronic)	**Who** Person in charge of shift/ Past op. **What** Investigate root cause of problem. Adjust times/temperatures to meet control specifications. **How** If fault cannot be fixed, stop production. **When** Immediately Inadequately pasteurised milk to be discarded if delay exceeds nominated time. **Records** Incident report.

Process Step	HAZARD	Status	Critical Limits	Monitoring	Corrective Actions	Records
3. a. Pasteurisation	Survival of pathogens due to inadequate pasteurisation	CCP	>65degrees C for ≥10 minutes.	What: Time and Temperature of milk How: Datalogger continuous recording of temperature Where: Cheese Vat When: During pasteurisation and data logger checked at completion of batch process Who: Cheesemaker	**Product:** If product has not been processed within critical limits, do not use - dispose. Contact Manager to assess and advise of next steps. **Who:** Cheesemaker **Process:** Conduct root cause analysis and implement actions to prevent recurrence. **Who:** Manager	Datalogger records, Logsheet – Specify specific form Identification
			Head space temperature Monitoring 65oC	What: Temperature of milk batch pasteruiser head space How: Thermometer reading of temperature headsapce Where: Batch Pasteuriser head space When: During pasteurisation at the beginning and completion of critical temperature cycle Who: Cheesemaker	**Product:** If head space is not within critical limits, do not use - dispose. Contact Manager to assess and advise of next steps. **Who:** Cheesemaker **Process:** Conduct root cause analysis and implement actions to prevent recurrence. **Who:** Manager	
			Indicating v Actual Thermometer 0.5oC	What: Temperature of milk How: Check that indicating thermometer and actual data logger thermometer are reading within 0.5oC Where: Cheese Vat When: During pasteurisation at the start of the critical temperature cycle Who: Cheesemaker	**Product:** If probes are not within critical limits 0.5oC, check calibration of probes. Contact Manager to assess and advise of next steps. **Who:** Cheesemaker **Process:** Conduct root cause analysis and implement actions to prevent recurrence. **Who:** Manager	

Licence Application Flowchart



Application Process

Before contacting the TDIA to apply for a processor's licence, you should:

1. Develop a business plan to ensure you have considered all cost contingencies

2. Ensure that at least one person from your organisation has attended recognised training and has the necessary skills, knowledge and competency to manage all the food safety aspects of your business (refer to Section 5 of this document, *Skills and Knowledge*).

3. Ensure your manufacturing premises complies with Standard 4.2.4 the *Primary Production and Processing Standard for Dairy Products* of the Food Standards Australia New Zealand Food Standards Code, including Chapters 3.2.2 and 3.2.3 of the FSANZ *Food Safety Standards.*

4. Notify and obtain local council planning approval for new or modified premises if required.

5. Develop a written food safety program based on Codex HACCP principles as outlined in Codex Alimentarius, Basic Texts on Food Hygiene, *Annex Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application*. The program must outline the control measures and procedures in place to prevent, reduce or eliminate food safety hazards associated with milk and dairy products at each point in the food manufacturing process. Refer to the FSANZ User Guide to Food Safety Programs, Standard 3.2.1.

6. Use these *Factory Requirements* as a guide to writing your food safety program. Some businesses choose to engage professional assistance in drafting a food safety program but care must be taken to ensure that you understand the program and can implement it fully when you commence operations.

7. Develop a microbiological and chemical testing program for raw materials (where relevant), product in process, and finished product. This must be included in your food safety program.

8. If you plan to export dairy products, contact the Department of Agriculture, Forestry and Fisheries. Businesses exporting must meet the regulatory requirements of the Export Control (Milk and Milk Products) Rules 2021 and be registered with the Commonwealth Department of Agriculture, Forestry and Fisheries.

9. If you intend to produce raw milk cheese you will need to address the additional requirements under Standard 4.2.4 in a documented and validated food safety program for TDIA approval.

It can take a while to write your Food Safety Program and then have it assessed and approved. You should allow up to 6 months, depending on the complexity of your business.

Developing and documenting your FSP and all associated records and forms is not easy, and you should ideally start the process at the same time you decide you want to produce dairy products. Food safety considerations will impact your business plan and budget and must be included in any business decisions. Getting it right the first time means you don't waste time and resources and make costly mistakes that need to be corrected later.

Consider the date you wish to commence operating, then work back and schedule appointments with all those you need to engage with, such as your local council, architect, trades people, milk supplier, packaging, chemicals, testing laboratory, TDIA, and so on.

Inspection, Audit and Approval Process

1. On-site preliminary visit or gap inspection (optional)

The purpose of this visit is to determine compliance with the hygienic and structural requirements, fixtures, fittings and equipment, of Chapter 3, Food Safety Standards, of the Food Standards Code and to identify any areas of concern for rectification prior to the initial audit. A preliminary site inspection will be undertaken if the applicant requests it.

2. Document Review

Prior to licence approval, the TDIA undertakes a comprehensive 'desk top audit' of your food safety plan, HACCP plan, policy manuals, procedures and other relevant supporting documentation that has been developed and documented by a competent person qualified in the principles and application of HACCP concepts.

This step gives you the opportunity to demonstrate that all documentation required by the TDIA has been prepared, is controlled where necessary, and is monitored and updated as required. Following this audit, TDIA provides a report on the documentation reviewed, broadly highlighting any deficiencies relevant to the application process. Deficiencies raised in this report must be addressed before approval is granted.

3. On-site verification

The purpose of this visit is to establish whether your food safety management system reflects practices, processes and complies with TDIA requirements. This is done by examining actual practices, documentation and records and comparing them against your policies, processes, procedures, (proposed product specs) and requirements of the Food Standards Code.

The auditor may present audit findings at the end of this audit, or soon after.

4. Licence Decision

If deficiencies are noted, approval is withheld until such time as they are rectified. Once you have met TDIA requirements, you will be issued a licence for the products specified in your application.

5. Audit and Review

After your licence has been issued, TDIA conducts on-site audits at periodic intervals. The frequency of these audits depends on the outcome, risk and the confidence held by TDIA in the effectiveness of your food safety management system. Such audits typically are announced, however, TDIA can and does conduct random unannounced audits.

Remember: Approval and assessment can be a lengthy process, with numerous iterations required in order to get your application right. Please allow for this in your application expectations.